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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,400	02/26/2002	Hans-Rainer Hoffmann	3868-0109P	3239

2292 7590 07/23/2004

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,400	Applicant(s) HOFFMANN ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 14 and 18 have been amended. New claim 19 has been added. Claims 1-19 are pending. Claims 1-13 have been withdrawn as being drawn to a non-elected invention. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant continues to traverse the initial restriction requirement that was made final in the previous Office action. Regarding Applicant's example from MPEP AI-67, this example would have unity of invention if Substance X were novel. In the instant case, the product of claim 1 is not novel, as set forth in the original restriction requirement. Furthermore, that a finding of lack of unity was not made in the IPER is not necessarily an indication of unity of invention. Such a finding, or lack thereof, does not set forth a directive for examination in the National Stage.

Claim Rejections - 35 USC § 103

Claims 14 and 16-18 are again rejected under 35 U.S.C. 103(a) as being unpatentable over ILLUM (US 5,863,554) and WUNDERLICH et al (US 5,932,245) in view of ROY et al (US 5,972,707), as set forth in the previous Office action. Newly added claim 19 is included in this rejection.

Note regarding claim interpretation: Claim 14 has been amended so that the product formed is a “dried nanosol.” However, a “nanosol” is defined as a colloidal disperse system, and a “colloid” is a substance that remains in suspension in a surrounding medium of a different matter. Drying the nanosol would appear to remove the surrounding medium and thus be a contradiction in terms. Therefore, a “dry nanosol” is being interpreted to mean that the product is in the form of a nanoparticulate.

Applicant’s arguments filed May 12, 2004 have been fully considered but they are not persuasive. Applicant first addresses ILLUM and WUNDERLICH in a piecemeal fashion at page 13, first two paragraphs of the remarks. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It was clearly acknowledged in the previous Office action that ILLUM did not teach nanosols, and WUNDERLICH did not teach chitosan.

Applicant further contends that ILLUM does not teach ionic bonding but that “the agent is ‘incorporated’ or ‘sorbed into’ the microspheres.” Because of this description, Applicant alleges that ILLUM’s process and product are fundamentally different from the instant invention. The examiner disagrees with the interpretation of ILLUM. The fact that the reference does not describe the interaction of the agent and chitosan at the bonding level does not change the fact that the combination of a negatively charged agent with a positively charged chitosan necessarily results in ionic bonding.

Applicant further states that the instant process is not a coacervation process as in ROY. Again, the difference in the process has been acknowledged. Regarding ROY, Applicant goes on

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to note that the instant process does not require the presence of two oppositely charged polymers. Neither does it preclude the presence of said polymers. Finally, Applicant notes "Roy discusses chitosan and not chitosan derivatives." However, Applicant's definition of "chitosan derivatives" includes "all modified and unmodified deacetylation products of chitin which still possess a polyglucosamine base structure."

The examiner maintains that it is known that chitosan and gelatin are capable of forming nanoparticulate products, or "dried nanosols." Chitosan and gelatin are known to be functional equivalents in drug delivery. Therefore, one of ordinary skill would be motivated to use the nanosol process of WUNDERLICH to prepare a chitosan-containing nanoparticulate product with a reasonable expectation of success. With regard to new claim 19, WUNDERLICH teaches particle size, as set forth in the previous Office action with several of the recited range exemplified in the examples. It would be within the scope of the artisan to prepare a product within this range for the art-disclosed utility.

Claims 14-18 are again rejected under 35 U.S.C. 103(a) as being unpatentable over ILLUM (US 5,863,554) and WUNDERLICH et al (US 5,932,245) in view of ROY et al (US 5,972,707) and further in view of SHINETSU (JP 6-211903), as set forth in the previous Office action. Newly added claim 19 is included in this rejection.

Applicant's arguments filed May 12, 2004 have been fully considered but they are not persuasive. Applicant adds no new arguments not addressed above. The addition of new claim 19 is addressed above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
July 15, 2004


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600